Remarks/Arguments

Status of Claims

Claims 1-20 were originally filed in the application. Claims 1-10 have been canceled. Claims 11-20 stand rejected under various rejections. No Claims have been amended; no Claims have been canceled; and no new Claims have been added. Therefore, Claims 11-20 are pending in this application.

Rejections

Claim Rejection – 35 USC § 103

Claims 11-20 are rejected under 35 USC 103(a) as being unpatentable over Leffell (US 4,894,547) in view of Trepagnier (US 2002/0016534). Applicants respectfully traverse this rejection.

The present invention as defined in Claim 11 relates to a method of determining the effect of a treatment to the skin of a subject. The method includes (i) exposing a first area of skin to a first exposure radiation to induce said area of skin to emit a first fluorescent emission, wherein said first exposure radiation comprises primarily of wavelengths of from about 290 nm to about 300 nm and wherein said first area of skin was exposed to said treatment; (ii) measuring the intensity of said first fluorescent emission having a wavelength of from about 320 nm to about 350 nm; (iii) exposing said first area of skin to a second exposure radiation to induce said area of skin to emit a second fluorescent emission, wherein said second exposure radiation comprises primarily of wavelengths of from about 330 nm to about 420 nm; (iv) measuring the intensity of said second fluorescent emission having a wavelength of from about 380 nm to about 470 nm; (v) calculating a ratio of said intensity measured in step (ii) to said intensity measured in step (iv); (vi) repeating steps (i) to (v) for a second area of skin, wherein said second area of skin was not exposed to said treatment; and (vii) comparing said ratio for said first area of skin to said ratio for said second area of skin;

and (viii) determining and reporting the effect of the skin treatment based on said compared ratios.

Leffell purports to disclose a method and apparatus for inducing fluorescence in human skin, in vivo, and for evaluating certain skin characteristics from the spectral intensity of induced fluorescence. Leffell purports to teach that an incident wavelength, e.g., 325 nm, induces fluorescence in a band from 350 nm to 750 nm. In particular, Lefell states:

> The resultant spectral waveform versus wavelength indicated a peak of fluorescence intensity at 390 nanometers, with a shoulder of the wave at 429 nanometers. A ratio of fluorescence intensity of these wavelengths was obtained and used to correlate the fluoresced skin with sun exposure.

(Col. 5, lines 1-6). In addition, Leffell teaches a ratio of sun-exposed skin to a control of non-sun-exposed skin (Col. 4, lines 56-58).

Before responding to the specific arguments made in the Claim Rejections portion, Applicants would like to request clarification of the arguments in the Office's "Response to Arguments." In particular, the Office appears to argue that Leffell teaches "studying a chemical compound such as tryptophan **or** NADH." Therefore, the Office argues that it is obvious to irradiate skin "at about a 295 nm wavelength and at a about 390-410 nm wavelength. . . as these are the wavelengths used to detect tryptophan **and** NADH." (emphasis added) (Office Action mailed 9/16/09, page 2). This seems to suggest that the Office believes that one of ordinary skill in the art, upon reading Leffell, may want to study **either** tryptophan **or** NADN. Therefore, a person wanting to study **only** tryptophan would excite fluorescence with incident wavelength bands necessary detect both tryptophan **and** NADH. A person wanting to study **only** NADH would excite fluorescence with incident wavelength bands necessary detect both tryptophan **and** NADH. Applicants respectfully submit that this does not seem logical, and they respectfully request clarification of this apparent inconsistency.

Turning to the specific arguments made in the Claim Rejections – 35 USC §103 section, the Examiner alleges that Leffell discloses a method utilizing light in **two different** pre-determined ultraviolet wavelength ranges and admits that Leffell does not

disclose Applicants claimed wavelength ranges. The Examiner then argues that Leffell discloses that **any two wavelength ranges** within the ultraviolet range can be used and further relies on Trepagnier for teaching monitoring cellular components such as tryptophan and NADH. Applicants respectfully disagree.

As a preliminary matter, Applicants respectfully submit that the portions of Leffell cited in the Office Action (Col. 2, lines 15-20 and 53-68, and Col. 4, lines 56-60) fail to teach or suggest the use of two different incident wavelength ranges. Indeed, the passage at Col. 2, lines 53-68, reads, "forming a ratio of the measured fluorescent intensity of skin." Thus, it is the fluorescent response at two different wavelengths that is determined and used to calculate a ratio. In marked contrast, Leffell specifically teaches the energy of a helium-cadmium laser having a wavelength of approximately 325 nm (see column 2, lines 24-27) is directed to a skin area to be evaluated by a fiberoptic element. This is a **single excitation** source. That Leffell employs a single excitation source to provide measurements used to calculate a ratio is described more clearly at Col. 5, lines 1-6, reproduced above. Perhaps what is confusing the Examiner is that Leffell then takes an **emission spectrum**, which traces the response from the 325 nm excited skin at various wavelengths (see column 4, lines 13-16). By doing so, Leffell can take the ratio of intensity of emission (from a single excitation wavelength) at 390 nm (peak) to 429 nm (shoulder). Applicants respectfully submit that Leffell does not teach or suggest exciting at a first wavelength, measuring the emission from the first excitation, exciting at a second wavelength, measuring the emission from the second excitation, and then calculating the ratio of the two emissions.

The Examiner also admits that the reference fails to disclose measuring fluorescent emission intensity at about 340 nm and about 440 nm. He then argues that it is well known that incident light at 295 nm causes fluorescence at about 345 nm and that incident light at about 370 nm causes fluorescence at about 420-570 nm, and seems to rely on the data in Table III of Leffell as suggestive of monitoring compounds at these wavelengths. Applicants point out that Leffell measured powdered or crystalline compounds to establish where they emit (see column 7, lines 27-30). Leffell utilized this data to demonstrate that his method measures elastin and desmosine (see

column 7, lines 48-57). Applicants respectfully submit that the method of the present invention is monitoring tryptophan (emission from about 320 nm to about 350 nm) and normalizing it to collagen (emission from about 380 nm to about 470 nm). This is neither taught nor suggested by Leffell. In fact, based on the data in Table III of Leffell, one might ask why would the present inventors monitor tryptophan when its intensity is 1/3 to 1/2 that of desmosine or elastin?

Trepagnier does not make up for the deficiencies in the teachings of Leffell. Trepagnier is focused on measuring blood analyte levels (such as glucose) by measuring transient changes in matrix chemistry (see paragraphs 0011, 0015, 0044, and 0045).

For the reasons outlined above, Applicants respectfully submit that the Office has failed to present a prima facie case of obviousness of Claims 11-20 in view of Leffell and Trepagnier. Reconsideration of this rejection is earnestly solicited.

Applicant believes that the foregoing presents a full and complete response to the outstanding Office Action. Applicant looks forward to an early notice of allowance for this application.

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